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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/796,239

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Fred T. Lee JR.

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BOYLE FREDRICKSON S.C.
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EXAMINER

SHAY, DAVID M

ART UNIT

PAPER NUMBER

3769

NOTIFICATION DATE

DELIVERY MODE

10/07/2009

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

docketing@boylefred.com

Office Action Summary	Application No. 10/796,239	Applicant(s) LEE ET AL.	
	Examiner david shay	Art Unit 3769	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on September 16, 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9, 13, 16-22, 28 and 29 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9, 13, 16-22, 28 and 29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on September 16, 2009 has been entered.

Firstly applicant argues that the limitations of claims 28 and 29 have not been addressed by the examiner. The examiner apologizes for any confusion on the part of applicant due to a any deficiency that may have been present in the explanation of the art, however, the examiner maintains that it would have been obvious to provide each shaft as a insulated metallic tubular member in a coaxial configuration, since this is not critical; is well within the skill of one having ordinary skill in the art; provides no unexpected result; and would make the device more sturdy, and to provide the insulating sleeve along at least the length of the trocar between the two sets of antenna, since this would prevent current from being grounded through the trocar, and to employ the trocars in a side by side configuration, rather than coaxial, since this is not critical; is well within the skill of one having ordinary skill in the art; provides no unexpected result; and would enable independent placement of the trocars. Next applicant asserts that the examiner "is not reading claim 29 as a whole, with the limitation of claim 1" This is true, however, since claim 29 depends from claim 16, this is also appropriate. As the limitations of claim 16 are obvious in view of the combination, so are the limitations of claim 29 as read by the examiner.

Next applicant asserts that the instant device has "clear advantages" over Gough et al '143, based on what applicant believes the reference "most probably" teaches. The examiner notes that there is no support in Gough et al '143 for the theory applicant puts forth as to it's

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operation, and the “clear advantages” are predicated on structure which is not claimed: the shafts being adjustably slidable with respect to each other. Thus these arguments are wholly unconvincing.

Continuing applicant asserts that the examiner “infers” structure in the device based on taking “a single sentence out of context”, the examiner cannot agree. As in the telephonic interview earlier, the examiner maintains that he disclosure of Gough et al '143 is directed to one of ordinary skill in the art, who being a surgeon well versed in applying electrical energy to tissue would be well aware of the need for insulation, in order to produce the ablation configuration discussed in the passages of Gough et al '143 discussed here. With regard to the axially separated planes and axially separated antennae, the examiner reiterates the well known nature of providing multiple parts for multiplied affect. A statement which applicant has steadfastly refused to comment on.

The arguments set forth in the previous office action are repeated here for completeness:

Firstly, applicant emphasizes that the claims are directed to a device having two shafts, and asserts that Gough et al ('143) is a single shaft device. The examiner must respectfully disagree. It is apparent from the disclosure of Gough et al ('143), specifically the embodiments relating to Figures 7 and 8 thereof, that the insulator, 18 can form a shaft to support the umbrella electrodes, in addition to the trocar, which forms another electrode support shaft. While applicants assert that the insulation cannot be considered an electrode support shaft, citing the disclosure of Gough et al ('143), which states that in one embodiment of the invention the insulation is “only semi-rigid”, it is unclear to the examiner why this prevents this embodiment of the insulator from being considered a “support shaft” within the broadest reasonable

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interpretation of the term. Firstly, there is no rigidity requirement with respect to the support shafts in the instant disclosure, in fact the terms rigid and flexible are entirely absent from the originally filed disclosure. Secondly, the insulator clearly functions as an element which contains, allows the deployment of, and maintains in position, a set of umbrella electrodes, and thus fulfills the function of a support shaft, the rigidity thereof notwithstanding. Lastly, Gough et al ('143) specifically teach that the rigidity of the antennas can be varied as desired (see column 5, lines 12-29).

Next, applicants argue that because the trocar of Gough et al ('143) is disclosed as made of metal with regards to Figures 1-5 thereof and since it is also illustrated with crosshatching indicating being composed of a metallic material, that trocar 14 in all embodiments of Gough et al ('143) must be composed of some sort of metal. With regard to the examiner's assertion that the concept of insulating the trocar is taught within the four corners of Gough et al ('143), albeit not *ipsis verbis*, applicants point to the discussion of the embodiment shown in Figure 5 of Gough et al ('143), noting that Gough et al ('143) does not specifically mention that the trocar be insulated and further asserts that it "is actually not certain that Gough '143 does in fact apply a bipolar signal across two sets of two axially spaced apart sets of umbrella electrodes" purportedly because the electrodes are all indicated with the numeral "16", Gough et al ('143) could be referring to two electrodes that are the same axial distance along the trocar (see the instant response, the sentence bridging pages 8 and 9 thereof). However, as set forth in the previous office action, the teachings of Gough et al ('143) must be evaluated for all its teachings, one of ordinary skill in the art, and not merely the preferred embodiments (see *In re Boe* 149 USPQ 507). One of ordinary skill in the art is a surgeon familiar with radiofrequency ablation of

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tumors, and as such, the training for one of ordinary skill in the art would require not only 12 years of primary and secondary school, but 4 years of college, 4 more years of medical school, and additional years as an intern before qualifying as a surgeon qualified to ablate tumors with radiofrequency energy. Of necessity, then one of ordinary skill in the art would also be familiar with basic electrical principles, such as the relationship of current and power, the appropriate connections required to cause electrical energy to be applied at the desired locations, and the ability of insulators to block the flow of electrical energy. Having established the level of skill of one of ordinary skill in the art, the information one of ordinary skill in the art would glean from the teachings of Gough et al ('143) will be determined. Firstly, Gough et al ('143) teach that the number of antennas can be more than six; the antennas can be deployed from the distal end of the trocar, while others, from along it's longitudinal axis; and that the device can be operated in a bipolar fashion, see column 3, lines 20-25:

“The number of deployed antennas can be four, five, six or more. Some of the antennas can be deployed out of the distal end of the trocar, while other antennas may be deployed from ports formed in the trocar along its longitudinal axis. The antennas may be RF electrodes operating in a monopolar mode, bipolar mode, or switchable between the two.”

Gough et al ('143) also teach that the electromagnetic delivery surface may be varied by varying the amount of the trocar and or antennas that are covered by the insulative sleeve, and that the insulative sleeve can contain apertures that permit the passage of antennae through the insulative sleeve while it is in place on the trocar, see column 5, lines 48-55:

“An insulation sleeve 18 may be positioned around an exterior of trocar 14 and/or antennas 16. All or some of insulation sleeves 18 may be adjustably positioned so that the length of an antenna electromagnetic energy delivery surface can be varied. Each insulation sleeve 18 surrounding a trocar 14 can

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include one or more apertures. This permits the introduction of a antenna 16 through trocar 14 and insulation sleeve 18.”

Gough et al ('143) also teach that when multiple antennae are used, the antennae may be operated in a bipolar mode, and that they may be multiplexed, see column 7, lines 21-34:

“As illustrated in FIG. 2, trocar 14 is introduced into a selected tissue mass 28. Three or more antennas 16 are positioned within a trocar lumen as trocar 14 is introduced into and through the selected tissue mass. In various embodiments, 3, 4, 5, or 6 antennas 16 are introduced laterally through trocar 14. Subsequently, antenna distal end 16' is advanced out of aperture 26 into selected tissue mass 28. Insulation sleeves 18 are adjusted for antennas 16. RF, microwave, short wave and the like energy is delivery to antenna 16 in a monopolar mode (RF), or alternatively, multiple antenna device 12 can be operated in a bipolar mode (RF). Multiple antenna device 12 can be switched between monopolar and bipolar operation and may have multiplexing capability between different antennas 16.”

Gough et al ('143) also teach that when multiple antennae are used, they can produce “a substantially complete ablation volume formed between antennas 16 with a minimal core that is not ablate” (see Figure 4, and column 8, lines 2-4), as one of ordinary skill in the art would readily appreciate, the only way a non-ablated core can be produced is if there is no current flowing between the antennae and the trocar, and this would enable one of ordinary skill in the art to conclude that the trocar is insulated to produce this effect. Still further, Gough et al ('143) also teach that when multiple antennae are used, the antennae may be situated at different axial positions along the trocar and “can be operated in a bipolar mode between the two antennas 16, or between a antenna 16 and trocar 14” (see Figure 5, and column 5, lines 9-11).

Given the totality of the teachings in Gough et al ('143), including those enumerated above, and taking these teachings in combination with the level of skill of one of ordinary skill in the art, as also set forth above, it is the examiner's view that the concept of bipolar application of

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energy to at least groups of antennae which are laterally distributed on the trocar is fairly taught thereby.

Continuing, applicants argue that this feature of Gough et al ('143) is not enabled under 35 U.S.C. 112, first paragraph, because Figure 10 does not show the precise connections to the antennas. This argument is not convincing, however. Firstly the level of skill of one of ordinary skill in the art, as set forth above, is sufficient to enable the production of the various configurations described by Gough et al ('143). Secondly the device of Gough et al ('143) is specifically recited as operating a bipolar mode in the claims thereof (see for example claim 16). Given the presumption of validity afforded issued US patents, applicants' conjecture that the use of bipolar mode in the device of Gough et al ('143) is insufficient to overcome this presumption.

Next applicants assert that, even assuming the examiner is correct, Gough et al ('143) do not teach a two shaft embodiment; "no three element assemblies" (presumably groups of three antennae) in Figure 8; and no predetermined spacing along the trocar in Figure 8, and thus a *prima facie* case of obviousness has not been established. The examiner must respectfully disagree. The two shaft issue has been discussed above, and thus Gough et al ('143) fairly teach the use of two shafts. Gough et al ('143) repeatedly stress that the number of antennae in the device can be varied as desired, and can exceed 6, as discussed with respect to the disclosure of Gough et al ('143) at column 3 thereof, above. This coupled with the fact that Gough et al ('143) seek to ablate tissue volumes would clearly lead one of ordinary skill in the art to employ e.g. 3 antennae in each group of the embodiment of Figure 8, or that discussed at column 3 of Gough et al ('143). Lastly, with respect to the predetermined spacing along the trocar, the use of the apertured insulator, discussed in column 5 of Gough et al ('143), as above, would require that the

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spacing be predetermined, since the aperture location would have to be predetermined.

However, even if this were not the case, to assert that one of ordinary skill in the art, as described above would be content to randomly position the antennae, rather than deliberately position them in a predetermined manner, so as to be sure to ablate the totality of the tumor while sparing as much healthy tissue as possible, strains the bounds of credulity. Thus applicants' arguments are not convincing.

Continuing, applicants query as to the examiner's meaning regarding the term define "an axially separated plane". The examiner was attempting to convey that the ablation volume produced by e.g. the setup of Figure 8, would intersect a plane which was aligned with the axis of the device and whose end points were at separate points along the axis of the device. The examiner apologizes for any confusion caused by the use of this term. With regard to the ablation volume produced by a device such as that shown in Figure 8 of Gough et al ('143) of described at column 3 thereof, firstly, current transferred between the two distalmost electrodes would "spread out radially from the electrode tip" (see Gough et al ('143), column 2, line 6), and would thus produce a "three dimensional volume" within the broadest reasonable interpretation of the term.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

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invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-9, 13, 16-22, 28, and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gough et al ('143) in combination with Swanson et al. Gough et al ('143) teach a device as claimed except for the specific disclosure that the current is passed from one electrode set to the other and the specific frequencies claimed. Swanson et al teach using frequencies in the 1 KHz range, to which tissue has a high resistivity. It would have been obvious to the artisan or ordinary skill to employ the frequencies in the 1 KHz range, since these are frequencies to which tissue has a high resistivity, as taught by Swanson et al, and would thus produce more heating, and to configure the device to produce current flow in the axial direction when there are multiple electrodes, since this would ablate the tumor more quickly than the procedure involving rotation, discussed by Gough et al ('143), and to provide multiple sets of electrodes with at least three electrodes, since this is not critical; is well within the skill of one having ordinary skill in the art; provides no unexpected result; and is merely the provision of multiplied parts for multiplied effect, to provide each shaft as a insulated metallic tubular member in a coaxial configuration, since this is not critical; is well within the skill of one having ordinary skill in the art; provides no unexpected result; and would make the device more sturdy, and to provide the insulating sleeve along at least the length of the trocar between the two sets of antenna, since this would prevent current from being grounded through the trocar, and to employ the trocars in a side by side configuration, rather than coaxial, since this is not critical; is well

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within the skill of one having ordinary skill in the art; provides no unexpected result; and would enable independent placement of the trocars, thus producing a device and method such as claimed.

Applicant's arguments filed March 6, 2009 have been fully considered but they are not persuasive. The arguments are not persuasive for the reasons set forth above.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to david shay whose telephone number is (571) 272-4773. The examiner can normally be reached on Tuesday through Friday from 6:30 a.m. to 5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry Johnson, can be reached on Monday through Friday from 7:00 a.m. to 3:30 p.m. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/david shay/

Primary Examiner, Art Unit 3769